In the United States Court of Federal Claims

No. 07-456V

(Filed: July 22, 2011)

W. C.,	)	Vaccine case; off-table claim involving multiple sclerosis allegedly caused by flu vaccine; alternative significant-aggravation off-table claim; entitlement issues; statutory criteria for redaction of identity or medical files and information; unwarranted invasion of privacy
Petitioner,	)	
v.	)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

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OPINION AND ORDER[1]

LETTOW, Judge.

Petitioner, W. C., seeks review of two decisions by a special master — one denying him compensation under the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 311, 100 Stat. 3743, 3755 (1986) (codified, as amended, at 42 U.S.C. §§ 300aa-1 to -34 ("Vaccine Act")), and another denying his motion to redact portions of the decision denying him compensation.

Mr. C. alleges that his receipt of a flu vaccine in December 2004 caused the onset of his multiple sclerosis or, alternatively, significantly aggravated his existing, but at the time asymptomatic, multiple sclerosis. *See W. C. v. Secretary of Health & Human Servs.*, No. 07-456

[1]In accord with the Rules of the Court of Federal Claims ("RCFC"), App. B, Rule 18(b), this opinion and order is initially being filed under seal. By rule, the parties are afforded fourteen days within which to propose redactions.

(Fed. Cl. Spec. Mstr. Feb. 22, 2011), ECF No. 68 ("Entitlement Decision") at 2.[2] The special master found that Mr. C. had developed multiple sclerosis before receiving the flu vaccine, but then also determined the record "d[id] not support a finding that Mr. C[.] ha[d] established . . . a medical theory causally connecting the flu vaccine to an aggravation of multiple sclerosis." Entitlement Decision at 24.

Subsequently, Mr. C. filed a motion requesting redaction of his name from the Entitlement Decision, pursuant to 42 U.S.C. § 300aa-12(d)(4)(B) and Vaccine Rule 18(b). Alternatively, Mr. C. moved that the decision be redacted to conceal the details of his medical condition. Both of petitioner's motions for redaction were denied. *See W. C. v. Secretary of Health & Human Servs.*, No. 07-456 (Fed. Cl. Spec. Mstr. Mar. 16, 2011), ECF No. 73 ("Redaction Decision") at 4.

In this court, petitioner seeks reversal of both of the special master's decisions, while respondent supports both decisions.

FACTS

A. *Mr. C.'s Medical History*

Mr. C. received the flu vaccination on December 13, 2004, when he was thirty-four years old. *See* Entitlement Decision at 2. Before December 13, Mr. C. was not displaying any clinical symptoms of neurological problems and described himself as healthy. *Id*.

On December 24, 2004, Mr. C.'s left arm and hand became numb. Entitlement Decision at 2. He also noticed numbness on the left side of his head and face. *Id*. The special master noted in the Entitlement Decision that both the petitioner's and the government's experts agreed that "Mr. C[.]'s report of numbness [was] the first expression of his neurological problem." *Id*. at 2-3.

Five days later, on December 29, Mr. C. saw his family doctor, Deborah Darrington, who recommended that Mr. C. undergo an MRI. Entitlement Decision at 3.[3] The MRI was

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[2]Multiple sclerosis is "a disease in which there are [centers] of demyelination throughout the white matter of the central nervous nervous system, sometimes extending into the gray matter; symptoms usually include weakness, incoordination, paresthesias, speech disturbances, and visual complaints." *Dorland's Illustrated Medical Dictionary* 1706 (31st ed. 2007). Demyelination is the "destruction, removal, or loss of the myelin sheath of a nerve or nerves." *Dorland's* at 493.

The myelin sheath is "the cylindrical covering of the axons on some neurons . . . consist[ing] of concentric layers of myelin . . . . Myelin is an electric insulator that serves to speed the conduction of nerve impulses." *Dorland's* at 1726; *see also id*. at 1237 (defining myelin).

[3]MRI stands for magnetic resonance imaging. *Dorland's* at 1203. An MRI uses magnetic fields and radio frequency waves to visualize structures in the body. To create an

performed on December 30, 2004, with and without a contrast agent. *Id*. A contrast agent, for example, gadolinium, can be used to determine if there is an existing breach in the blood-brain barrier. *Id*. at 9. Gadolinium is injected into a person's blood. If there is an existing breach, the gadolinium enters the brain, and lesions[4] in the brain appear "enhanced" on the MRI. *Id*. When there has been damage to the blood-brain barrier, but the body has repaired the damage at least to the extent that the breach no longer exists as an active matter, lesions will no longer appear enhanced. *Id*.

Dr. Jason Arthur, the interpreting physician, reported,

> Scattered nonspecific T2 high signal lesions are noted in the deep white matter. Findings on MRI in conjunction with the patient's clinical history suggest multiple sclerosis as a possible etiology. There is focal high T2 signal intensity lesion within the anterior aspect of the corpus callosum on the right and within the posterior body of the corpus callosum within the midline. There are no focal contrast enhancing lesions.

Ex. 1 at 27 (Report of Dr. Arthur (Dec. 30, 2004)) (quoted in Entitlement Decision at 3).[5] Dr. Arthur's observation that there were "no focal enhancing contrast lesions" indicates that any blood-brain barrier disruption had healed prior to the MRI conducted on December 30th.

Mr. C.'s symptoms abated but then reappeared during a deer hunting expedition on January 8, 2005. Entitlement Decision at 3. That night, he lost most motor functions in his left hand and arm. *Id*. Two days later, Mr. C. saw a neurologist, John Hannam. Dr. Hannam commented, "[T]he MRI findings . . . conceivably could be explained by multiple sclerosis and it is possible that the recent onset of his left sided tingling and numbness represents the first clinical attack." *Id*. (quoting Ex. 1 at 34 (Notes of Dr. Hannam (Jan. 12, 2005))). Dr. Hannam also requested an analysis of Mr. C.'s spinal fluid. The analysis showed the absence of oligoclonal bands in the fluid. Dr. Hannam commented at the time, "[I]t remains unclear whether [Mr. C.] does or [does] not have [multiple sclerosis]." Entitlement Decision at 3 (quoting Ex. 1 at 50 (Notes of Dr. Hannam (Jan. 19, 2005))).

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image, a patient is positioned within a magnetic field as radio wave signals are conducted through a selected part of the body. Energy is absorbed by tissues and then released. *Stedman's Medical Dictionary* B13 (28th ed. 2006).

[4]A lesion is "any pathological or traumatic discontinuity of tissue or loss of function of a part." *Dorland's* at 1039.

[5]Exhibits submitted by the parties will be cited by their assigned number. References to the transcript of the hearings conducted by the special master will be to "Tr. __." In contrast, the transcript of the hearing conducted by the court on June 14, 2011 will be cited as "Hr'g Tr. __."

Five days later, Mr. C. called Dr. Hannam because someone had told him about Guillain-Barré syndrome, which may be caused by flu vaccines. Entitlement Decision at 3.[6] Mr. C. informed Dr. Hannam that he had received a flu shot eleven days before his symptoms appeared. *Id*. Dr. Hannam responded that his clinical findings did not support a diagnosis of Guillain-Barré syndrome. *Id*. During the phone call, Mr. C. also reported that his symptoms were improving. *Id*.

Mr. C. returned to Dr. Hannam for an office visit on February 22, 2005. He reported some tingling in the tips of the finger of his left hand and "remain[ed] suspicious that there [was] a causal connection between his symptoms and receiving the flu shot." Entitlement Decision at 4 (quoting Ex. 1 at 50 (Notes of Dr. Hannam (Feb. 22, 2005))). Dr. Hannam told Mr. C. that the evidence indicated he did not have Guillain-Barré, but showed that he might have developed multiple sclerosis. *Id*. Dr. Hannam wrote in his notes that "if [Mr. C.] had [multiple sclerosis], [he] c[ould]n't blame it on the flu shot." *Id*. (quoting Ex. 1 at 50). Dr. Hannam recommended that Mr. C. consult with another doctor, Rifaat Bashir, who specialized in multiple sclerosis, and his family doctor, Dr. Darrington, concurred with Dr. Hannam's suggestion.

Mr. C. met with Dr. Bashir on March 22, 2005. At that time, he told Dr. Bashir that his "main symptoms are sensory and come on with exercise." Entitlement Decision at 4. Dr. Bashir conducted a neurological examination and concluded,

> I believe that Mr. C[.] had [a] clinically isolated syndrome in December [2004] that gave him the sensory changes in his left upper extremity and neck. His head MRI scan is . . . consistent with a demyelinating disease. He could have had a single isolated event possibly related to his vaccination which he did receive about two weeks before the event. At this point in time, I am not absolutely sure whether he is going to progress to multiple sclerosis or not. If he develops another event in another area[,] th[e]n he certainly has the condition. Another way to arrive at the diagnosis would be to repeat his MRI scan of the head and cervical spine and see if he has any new lesions. If he does, one can make a diagnosis of . . . multiple sclerosis.

Ex. 1 at 46 (Letter from Dr. Bashir to Dr. Darrington (Mar. 22, 2005)).

Mr. C. had another MRI on March 23, 2005, which showed "[t]hree small foci of signal abnormality . . . show[ing] no mass-effect or pathologic-enhancement." Ex. 7 at 31. On April 6,

[6] Guillain-Barré syndrome is also known as "acute idiopathic polyneuritis," which is a "rapidly progressive ascending motor neuron paralysis of unknown etiology . . . . It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face." *Dorland's* at 822, 1513. It has been postulated that the cause of Guillain-Barré is an autoimmune reaction, in which the body develops an immune response to, and attacks, its own tissues. *Id*. at 183, 1513.

2005, Mr. C. returned to Dr. Bashir, who reported that the MRI "showed findings consistent with [acute disseminating encephalomyelitis ('ADEM')]."[7] Entitlement Decision at 4 (citing Ex. 7 at 9-10; Neil M. Davis, *Medical Abbreviations* 39 (12th ed. 2005)). Dr. Bashir ordered nerve conduction studies, which were normal, and an electromyography ("EMG"),[8] which showed no evidence of denervation. Entitlement Decision at 4.[9] At Mr. C.'s next appointment with Dr. Darrington, Mr. C. told her that "Dr. Bashir [felt] that [Mr. C.'s] symptoms could represent an acute [demyelinating] polyneuropathy . . . [or] could . . . represent early multiple sclerosis." *Id*. at 4-5 n. 1 (quoting Ex. 1 at 5 (Notes of Dr. Darrington (May 11, 2005))).[10]

Mr. C. had another MRI on June 28, 2005, which showed the same three lesions described in the March 23, 2005 MRI. Entitlement Decision at 5. The examining doctor also reported seeing a "new very ill-defined 7.9 mm focus of signal abnormality," which was the only lesion showing enhancement. *Id*. (quoting Ex. 7 at 25 (Report of Dr. Bashir for Exam Date June 28, 2005)). The doctor concluded Mr. C.'s condition "likely . . . represent[ed] [a]cute [d]isseminating [e]ncephalomyelitis since there ha[d] been interval worsening and not improvement" in the intervening months, but that a "white matter demyelineating process such as multiple sclerosis w[ould] have to be considered in the differential diagnosis." Ex. 7 at 26; *see also* Entitlement Decision at 5.

On June 28, 2005, Dr. Bashir sent a letter to Dr. Darrington, stating, "In view of the new area of enhancement[,] I think a diagnosis of clinically supported [multiple sclerosis] can be made." Ex. 7 at 7 (Letter from Dr. Bashir to Dr. Darrington (June 28, 2005)). Dr. Bashir wrote a prescription for Mr. C. and proceeded to treat Mr. C. for multiple sclerosis. Entitlement Decision at 5.

B. *Multiple Sclerosis*

Multiple sclerosis is a disorder of the central nervous system. Entitlement Decision at 5. In multiple sclerosis, parts of the central nervous system are subject to an autoimmune attack and

[7]Acute disseminating encephalomyelitis is an acute or subacute inflammation of the brain and spinal cord, or an inflammation of the spinal cord characterized by a perivascular lymphocyte and mononuclear cell infiltration and demyelination. *Dorland's* at 621, 1237 (defining acute disseminating encephalomyelitis and myelitis, respectively); *see also id*. at 950 (defining infiltration as "the pathological accumulation in tissues or cells of substances not normal to it or in amounts in excess of the normal").

[8]An EMG or electromyography is "an electrodiagnostic technique for recording the extracellular activity . . . of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." *Dorland's* at 609.

[9]Denervation is the "resection or removal of the nerves to an organ or part." *Dorland's* at 493.

[10]Demyelinating polyneuropathy is "any . . . neurologic condition[] in which demyelination of multiple nerves is the primary symptom." *Dorland's* at 1513.

experience inflammation with resulting demyelination. *Id*. Multiple sclerosis occurs at a rate of about one case per one thousand people. *Id*.

For many years, researchers have considered multiple sclerosis to be an autoimmune disease,[11] although other theories of pathogenesis are being explored. Entitlement Decision at 5. These alternative theories include the postulate that multiple sclerosis is a neurodegenerative disorder, *id*. (citing Ex. C, Tab 2 (Bruce D. Trapp & Klaus-Armin Nave, *Multiple Sclerosis: An Autoimmune or Neurodegenerative Disorder*, 31 Ann. Rev. Neurosci. 247, 247 (2008))), based in part on research showing that inflammation of the central nervous system in mice can be produced without nerve dysregulation. *Id*. (citing Tr. 173-78; Ex. C, tab 1, Henry F. McFarland & Roland Martin, *Multiple Sclerosis: A Complicated Picture of Autoimmunity*, 8 Nature Immunology 913 (2007)). The cause of multiple sclerosis is not known, but members of the medical community believe that it starts when there is a breach in the barrier separating the blood in the circulatory system from the brain. Entitlement Decision at 6. Immune system cells cross into the brain and mistakenly attack parts of the central nervous system. These attacks lead to inflammation and to the formation of lesions. *Id*. (citing Ex. C, Tab 2 (Trapp & Nave, at 248-49)).

Multiple sclerosis is classified into different types. The most common type of multiple sclerosis, and the type afflicting Mr. C., is known as relapsing remitting multiple sclerosis. Entitlement Decision at 6. A more severe form, chronic progressive multiple sclerosis, is markedly more disabling. People with relapsing remitting multiple sclerosis usually have approximately one relapse of multiple sclerosis per year. *Id*. Like the cause of the onset of multiple sclerosis, the cause of relapses of multiple sclerosis is not known. *Id*.

C. *The Special Master's Decision*

In June 2007, Mr. C. filed his petition for vaccine compensation and medical records, claiming that the flu vaccination had caused his multiple sclerosis. In response to Mr. C.'s petition, the government recommended that compensation be denied, arguing that Mr. C. had not offered "a reputable medical or scientific theory causally connecting the vaccine to any alleged injury." Entitlement Decision at 6 (quoting Resp't's Report at 10).

In support of his petition, Mr. C. submitted a report and associated medical pages and literature from his expert, Dr. Carlo Tornatore, the director of the Multiple Sclerosis Center at Georgetown University Hospital. Dr. Tornatore opined that the influenza vaccination caused Mr. C.'s multiple sclerosis. Entitlement Decision at 6. To explain how the influenza vaccine could cause multiple sclerosis, Dr. Tornatore relied upon the theory of antigen cross-reaction, also known as molecular mimicry. *Id*. at 7. Dr. Tornatore cited various medical textbooks and case reports that have reported "an association between influenza vaccine and a number of autoimmune disorders." *Id*. (quoting Ex. 12 at 14 (Expert Report of Dr. Tornatore (Feb. 22,

[11] An autoimmune disease is "a disorder caused by an immune response directed against self-antigens." *Dorland's* at 536. Self-antigens, or autoantigens, are antigens that, "despite being a normal tissue constituent, [are] the target of a humoral or cell-mediated immune response." *Id*. at 107, 182.

2008) (ECF No. 15))). Additionally, Dr. Tornatore observed that there was a "temporal relationship [between] the vaccination and the onset of symptoms." Entitlement Decision at 7 (quoting Ex. 12 at 15).

In response to Dr. Tornatore's report, the government proffered an expert report from Dr. Arun Venkatesan. Dr. Venkatesan is an assistant professor in the Department of Neurology at Johns Hopkins University. In his expert report, Dr. Venkatesan concluded that "the influenza vaccination did not cause" Mr. C.'s multiple sclerosis and that "the medical literature does not support a biologically plausible link between influenza vaccination and [multiple sclerosis]." Entitlement Decision at 7 (quoting Ex. A at 1, 3 (Expert Report of Dr. Venkatesan (May 20, 2008)) (ECF No. 18))).

A hearing was held in Washington, D.C., on November 4, 2008, at which Dr. Tornatore and Dr. Venkatesan both testified. During this hearing, Dr. Venkatesan opined, for the first time, that the lesions detected in the MRI conducted on December 30, 2004 must have existed for at least three weeks prior to December 30, because they had not shown enhancement in the MRI. Entitlement Decision at 8 (citing Tr. 144:8 to 145:23 (Nov. 4, 2008) (Test. of Dr. Venkatesan)). Dr. Venkatesan asserted that studies have measured the duration of lesion enhancement and, according to these studies, new lesions tended to show enhancement for an average of three weeks or longer. Tr. 144:12 to 145:8 (Nov. 4, 2008). He believed the unenhanced lesions detected in the MRI conducted on December 30, 2004 were "unlikely" to be new enough to have been caused by the flu vaccine. Tr. 145:4-8 (Nov. 4, 2008); Entitlement Decision at 8. After the hearing, the government was asked to supply the articles on which Dr. Venkatesan relied for this assertion. Entitlement Decision at 8.

Respondent filed the requested materials, and Mr. C. was given an opportunity to obtain and provide a supplemental report from Dr. Tornatore, which was filed on March 9, 2009. Entitlement Decision at 8. Dr. Tornatore stated the duration of enhancement was shorter than the period suggested by Dr. Venkatesan, and that the non-enhanced lesions on Mr. C.'s December 30, 2004 MRI could have been caused by the December 13, 2004 flu vaccination. *Id*. (citing Ex. 27 at 2-3 (Supplemental Expert Report of Dr. Tornatore (Mar. 7, 2009))). The competing views regarding the onset of Mr. C.'s lesions were the subject of a second hearing, held on November 17, 2009.

After the second hearing, the parties filed briefs and the special master issued a decision denying Mr. C.'s petition for compensation. The special master found that Mr. C. had sub-clinical multiple sclerosis before his vaccination, *see* Entitlement Decision at 13; and that the flu vaccine did not significantly aggravate Mr. C.'s multiple sclerosis. *Id*. at 23-24.

Following the decision, Mr. C. filed motions requesting redaction of his name, or alternatively, information concerning his medical condition, from the Entitlement Decision pursuant to 42 U.S.C. § 300aa-12(d)(4)(B) and Vaccine Rule 18(b). He argued that revealing his name in connection with his medical condition would constitute an "unwarranted invasion of privacy" because, through his work at a federal governmental department, he frequently testifies "on behalf of the government in cases involving criminal and administrative violations of immigration and nationality laws." Aff. of W. C. at 2 (Mar. 3, 2011). Mr. C. expressed concern

that the public release of his identity with information concerning his medical condition "could be used to discredit" his testimony. *Id*. Both of petitioner's motions for redaction were denied.

Mr. C. has moved for review by this court of the special master's decisions on entitlement and redaction. Having been briefed and argued, the issues are ready for disposition.

ANALYSIS

I. Entitlement Decision

Mr. C. seeks review of the special master's Entitlement Decision on several grounds. Mr. C. argues that the special master did not properly analyze the theory that the flu vaccine caused his multiple sclerosis (his "direct-causation claim") under *Althen*, and that the special master's conclusion that Mr. C. had pre-existing subclinical multiple sclerosis was arbitrary and capricious. Pet'r's Mem. at 10, 13, 18. Mr. C. also contends that the special master did not use the correct legal standard to evaluate his substantial-aggravation claim, and that the special master's finding that the flu vaccine did not substantially aggravate Mr. C.'s multiple sclerosis was arbitrary and capricious. *Id*. at 26, 28.

A. *Standards for Review*

Upon review of a special master's decision, the court does not "reweigh the factual evidence," "assess whether the special master correctly evaluated the evidence," or "examine the probative value of the evidence or the credibility of the witnesses." *Lampe v. Secretary of Health & Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotation marks omitted) (quoting *Munn v. Secretary of Health & Human Servs.*, 970 F.2d 863, 871 (Fed. Cir. 1992)). "[R]eversible error is 'extremely difficult to demonstrate' if the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" *Lampe*, 219 F.3d at 1360 (quoting *Hines ex rel. Sevier v. Secretary of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)). Nonetheless, this court must "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B).

The Vaccine Act provides for two means of recovery: table claims and off-table claims. "In a table claim, a claimant who shows that he or she received a vaccination listed in the Vaccine Injury Table ('table'), 42 U.S.C. § 300aa-14, and suffered an injury listed in the table within a prescribed period is afforded a presumption of causation." *Andreu v. Secretary of Health & Human Servs.*, 569 F.3d 1367, 1374 (Fed. Cir. 2009). By contrast, a petitioner making an off-table claim is required to prove actual causation by a preponderance of the evidence. *See Moberly v. Secretary of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010). To prove actual causation, a petitioner must "show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Id.* at 1321-22 (quoting *Shyface v. Secretary of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)).

Mr. C. has proffered two alternative theories under which he could recover on his off-table claim — that the flu vaccine caused his multiple sclerosis, and that the flu vaccine significantly aggravated pre-existing multiple sclerosis. To prevail on his direct-causation claim, Mr. C. must prove three different, but largely overlapping, elements:

> (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). A plaintiff must satisfy all three of *Althen*'s prongs by preponderant evidence. *See Capizzano v. Secretary of Health & Human Servs.*, 440 F.3d 1317, 1327 (Fed. Cir. 2006). In making this showing, "evidence used to satisfy one of the *Althen* . . . prongs can[] overlap to satisfy another prong." *Id.*[12] "A petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" *Moberly*, 592 F.3d at 1322 (quoting *Knudsen v. Secretary of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994)).

To prevail on his alternative claim that the flu vaccine significantly aggravated his multiple sclerosis, Mr. C. must establish six elements. As this court explained in *Loving v. Secretary of Health & Human Services*, 86 Fed. Cl. 135, 144 (2009), a petitioner can prevail on a significant-aggravation off-table claim by establishing the three direct-causation *Althen* prongs as well as three elements articulated by the Federal Circuit in *Whitecotton v. Secretary of Health & Human Services*, 81 F.3d 1099, 1107 (Fed. Cir. 1996). In *Whitecotton*, the Federal Circuit articulated a four-part test to govern significant-aggravation for table claims. 81 F.3d at 1107. The fourth prong of the *Whitecotton* test required reference to the vaccine table, but it essentially aimed at determining whether the aggravation could have been caused by the vaccine. This court reasoned in *Loving* that an appropriate test for significant-aggravation off-table claims would be to consider the first three prongs articulated in *Whitecotton* in combination with the three *Althen* prongs, which set forth a means to establish causation in off-table claims. Accordingly, for a petitioner to establish that a vaccine significantly aggravated an existing ailment in an off-table claim, the petitioner must show preponderant evidence of:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent),

[12]For example, in *Capizzano*, the petitioner had satisfied the first and third prongs of *Althen*. *See* 440 F.3d at 1326 ("[T]he first prong of the *Althen* . . . test was satisfied by the finding that the hepatitis B vaccine can cause RA [rheumatoid arthritis]. The third prong was satisfied by the finding that Ms. Capizzano's RA appeared within days of receiving the vaccine.") (citations omitted). Regarding the second prong, the court of appeals concluded that the special master had "erred in not considering the opinions of the treating physicians who concluded that the vaccine was the cause of Ms. Capizzano's injury." *Id.*

> (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144.

Under either of Mr. C.'s theories, he must establish his case by preponderant evidence. The preponderant-evidence standard requires that a petitioner demonstrate proof "by a simple preponderance, of 'more probable than not' causation." *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Secretary of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). This standard "simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *Moberly*, 592 F.3d at 1322 n.2 (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Construction Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993)). As applied to vaccine cases, the preponderant standard means that although a claimant must provide a plausible medical theory, a claimant need not offer "identification and proof of specific biological mechanisms[—a requirement that] would be inconsistent with the purpose and nature of the vaccine compensation program." *Knudsen*, 35 F.3d at 549; *see also Capizzano*, 440 F.3d at 1325; *Althen*, 418 F.3d at 1280. Thus, "[t]he fact that a link between a vaccine and a particular injury is a 'sequence hitherto unproven in medicine' will not bar recovery, because 'the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.'" *Rotoli v. Secretary of Health & Human Servs.*, 89 Fed. Cl. 71, 79 (2009) (quoting *Althen*, 418 F.3d at 1280); *see also Capizzano*, 440 F.3d at 1324.

The Vaccine Act provides that a claimant may satisfy the preponderance standard "by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1). Accordingly, a special master may not require "'epidemiologic studies . . . or general acceptance in the scientific or medical communities'" because such prerequisites would "'impermissibly raise[] a claimant's burden.'" *Andreu*, 569 F.3d at 1378 (quoting *Capizzano*, 440 F.3d at 1325-26); *see also Moberly*, 592 F.3d at 1325; *Althen*, 418 F.3d at 1280 (holding that requiring a claimant to provide "medical literature" "contravenes section 300aa-13(a)(1)'s allowance of medical opinion as proof"). Nor may the special master require a claimant to present proof of pathological markers or genetic predisposition to an adverse immunological response. *See Capizzano*, 440 F.3d at 1325-26. To the contrary, the Federal Circuit has explained that "the use of circumstantial evidence [is] envisioned by the preponderance standard." *Althen*, 418 F.3d at 1280; *see also Andreu*, 569 F.3d at 1379 ("[A] paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery."). "Thus, for example, causation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular [claimant] without detailed medical and scientific exposition on the biological mechanisms." *Knudsen*, 35 F.3d at 549.

Equally importantly, special masters in Vaccine Act cases are "entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Additionally, where epidemiological evidence or medical literature is submitted, "the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury." *Andreu*, 569 F.3d at 1379. Such evidence, however, must be viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380.

In sum, there are no "hard and fast *per se* scientific or medical rules" for finding causation under the Vaccine Act. *Knudsen*, 35 F.3d at 548. It is evident, however, that "[t]he Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims." *id.* at 549, and "close calls regarding causation are [to be] resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

B. *Petitioner's Direct-Causation Claim*

1. *The starting point of the special master's analysis.*

In his Entitlement Decision, the special master began his analysis by first determining whether or not Mr. C. already had multiple sclerosis when he received the flu vaccine. *See* Entitlement Decision at 9. After concluding that Mr. C.'s multiple sclerosis predated the flu vaccination, the special master only explicitly analyzed whether the vaccination significantly aggravated Mr. C.'s multiple sclerosis. *See id*. at 13.[13]

Mr. C. criticizes the special master's analysis from two perspectives. First, he argues that the special master erred by choosing which of petitioner's theories to analyze, instead of analyzing both. Second, and relatedly, he claims that the special master was required to analyze his theory that the flu vaccine caused his multiple sclerosis under *Althen*, and failed to do so.

In choosing to first determine whether Mr. C. had preexisting multiple sclerosis, the special master relied on *Broekelschen v. Secretary of Health & Human Services*, 618 F.3d 1339 (Fed. Cir. 2010). *Broekelschen* stands for the proposition that, when "the injury itself is in dispute, the proposed injuries differ significantly in their pathology, and the question of causation turns on which injury [the petitioner] suffered," it is "appropriate . . . for the special master to first determine which injury [i]s best supported by the evidence presented in the record before applying the *Althen* test." *Id*. at 1346. In *Broekelschen*, the parties disputed which disease the petitioner suffered — transverse myelitis or anterior spinal artery syndrome. *Id*. While these two conditions had "overlapping symptoms, their underlying causes or etiology are completely different." *Id*.

[13]The special master concluded that "the record . . . supports a finding that Mr. C[.]'s lesions existed before the vaccination. This finding necessarily means that Mr. C[.] cannot prevail on his theory that the flu vaccine caused his multiple sclerosis." Entitlement Decision at 13.

In holding that "identifying the injury is a prerequisite to the [*Althen*] analysis," 618 F.3d at 1346, the court of appeals in *Broekelschen* distinguished the facts before it from those of two other vaccine cases, *Andreu*, 569 F.3d 1367; and *Kelley v. Secretary of Health & Human Services*, 68 Fed. Cl. 84 (2005). In *Andreu*, the parties disputed whether the petitioner suffered from a febrile or afebrile seizure in response to receipt of the DPT vaccine. However, the Federal Circuit held that an exact diagnosis was not required to determine whether the vaccine caused the petitioner's injury, because both parties agreed that "whatever caused [the petitioner's] first seizure also led to his subsequent seizure disorder." *Andreu*, 569 F.3d at 1381. Similarly, in *Kelley*, the petitioner was not required to classify his injury precisely where the two possible diagnoses were "variants of the same disorder." 68 Fed. Cl. at 100-01.

In Mr. C.'s case, the nature of his injury is not in question. Mr. C. suffers from multiple sclerosis and suffered several episodes of multiple sclerosis following his flu vaccination. Accordingly, *Broekelschen* is inapposite and the special master should have evaluated *both* whether the flu vaccine caused and whether it significantly aggravated Mr. C.'s multiple sclerosis.

Nonetheless, although the special master did not explicitly conduct an *Althen* analysis on Mr. C.'s claim that the flu vaccine directly caused his multiple sclerosis, he performed such an analysis implicitly. The special master's conclusion that Mr. C's lesions existed before the vaccination bears on the second and third prongs of *Althen*. The second prong of *Althen* looks to whether "it is logical to conclude that the vaccine was the cause of [the injury] (the effect)." *Capizzano*, 440 F.3d at 1326. If Mr. C. developed multiple sclerosis before he received the flu vaccine, then he cannot establish "a logical sequence . . . showing that the vaccination was the reason" for his multiple sclerosis, because the multiple sclerosis existed before the vaccination. *See Althen*, 418 F.3d at 1278. Correspondingly, the third prong of *Althen* "requires preponderant proof that the onset of symptoms occurred within a time[ ]frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Secretary of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008); *see also Pafford v. Secretary of Health & Human Servs.*, 451 F.3d 1352, 1358 (Fed. Cir. 2006) ("Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters the link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis."). If Mr. C. became ill before receiving the vaccine, *a fortiori*, he cannot show that his acquiring multiple sclerosis "occurred within a medically acceptable time frame" of the vaccination to demonstrate that the vaccine was a 'but-for' cause of his multiple sclerosis. *Pafford*, 451 F.3d at 1358. Thus, the special master's mistaken analysis under *Broekelschen* can be understood as an implicit finding that Mr. C. did not satisfy *Althen* prongs two and three and therefore did not establish by preponderant evidence that his vaccination caused his multiple sclerosis.

2. *The special master's core factual findings.*

Mr. C. next urges the court to hold that the special master's factual finding that Mr. C. had subclinical multiple sclerosis prior to his flu vaccination was arbitrary, capricious, and an abuse of discretion. Pet'r's Mem. at 13.

The disagreement between petitioner's expert, Dr. Tornatore, and the government's expert, Dr. Venkatesan, about when Mr. C. contracted multiple sclerosis turned on the fact that the lesions that appeared in Mr. C.'s MRI conducted on December 30, 2004 did not appear to be enhanced. In Dr. Venkatesan's view, if the lesions had not developed until after Mr. C.'s vaccination, "at least one of them [still] should have been enhanced when the MRI was done[, seventeen] days after [the] vaccination." Entitlement Decision at 11 (citing Tr. 289:2-19 (Nov. 17, 2009) (Dr. Venkatesan)); *see also* Tr. 289:2-19 (Dr. Venkatesan) ("I felt it would be unlikely that those [six] lesions [observed in the December 30 MRI] would not be enhancing, given the timespan between the vaccination and the MRI scan. . . . I was quite surpris[ed] none of them were."). In contrast, Dr. Tornatore believed there was enough time following Mr. C.'s vaccination for lesions to have developed and healed. *See* Tr. 339:10 to 341:9 (Nov. 17, 2009) (Dr. Tornatore).

The special master found Dr. Venkatesan's reasoning more persuasive, and explained how he reached this opinion by reference to a study reported in 2003. *See* Ex. 27, Tab A (Francois Cotton, et al., *MRI Contrast Uptake in New Lesions in Relapsing-Remitting MS Followed at Weekly Intervals*, 60 Neurology 640 (2003)). The Cotton study performed weekly MRIs on patients to obtain information on how long lesions remained enhanced. *See id*. at 640. Because of the weekly interval, the gathered data was necessarily somewhat imprecise. For example, a lesion in the Cotton study which showed up as enhanced in one scan but not another could have been enhanced anywhere from one to thirteen days. It could have been enhanced only the date the MRI was performed, lasting one day, or it could have developed the day after the previous week's MRI, persisted seven days until the MRI in which it appeared enhanced, and then another six days until the day before the next weekly MRI. *See* Entitlement Decision at 10 (illustrating this point with a calendar). Similarly, a lesion which showed enhancement in two weekly scans could have been enhanced from eight to twenty days, a lesion which showed enhancement in three weekly scans could have been enhanced fifteen to twenty-seven days, etc.

Cotton observed twenty-six patients and calculated the mean and median duration of lesion enhancement. The mean duration was 3.07 weeks; the median was 2 weeks. *See* Ex. 27, Tab A, at 640. The special master noted that Dr. Tornatore believed relying on the median to estimate the life of a lesion was more useful, because it would prevent outlying numbers from skewing the estimated time frame. Entitlement Decision at 11; *see also* Tr. 342:3 to 20 (Nov. 17, 2009) (Dr. Tornatore) ("[I]f you have a spectrum of data points, but there are outliers that will skew the data, the median is a better indicator of what you should look at. And in this case[,] the median was . . . two weeks . . . . [M]ost lesions will not enhance for more than two weeks.")

Two weeks and three days passed between the administration of Mr. C.'s vaccination and the MRI on December 30, 2004. The MRI detected six unenhanced lesions. Under Dr. Tornatore's theory of how the flu vaccine could cause multiple sclerosis, the process of forming lesions "would take at least a few days and potentially even a week or two." Tr. 302:4-5 (Nov. 17, 2009) (Dr. Tornatore); *see also* Tr. 313:6-13 (Nov. 17, 2009) (Dr. Venkatesan) ("[I]f there were a vaccine associated inflammatory response that represented the beginning of [multiple sclerosis,] what I would expect to happen would be that in a few days, perhaps even in a week or two, . . . lesions would develop.").

The special master reasoned that, if the lesions had been formed three days after the vaccination, on December 16, they would have been two weeks old on the date of Mr. C.'s MRI on December 30. *See* Entitlement Decision at 12. According to the Cotton study, about half of all lesions appear enhanced after two weeks, and half have healed enough not to show enhancement. *See* Ex. 27, Tab A, at 640. The special master was persuaded that it was more likely than not that lesions appeared before a time when they could have been caused by the flu vaccine. The special master took particular note that six lesions appeared in the MRI conducted on December 30. He reasoned that, although one lesion had about a 50% chance of becoming unenhanced within two weeks, the chances that all six lesions would have developed and then healed in two weeks was very low. Entitlement Decision at 12.[14] He also recognized that although the lesions could have been formed as early as a few days after the vaccination, they could have formed much later, under Dr. Tornatore's own hypothesis. *Id*.

The special master explained, "It is important to emphasize the standard for finding the duration of Mr. C.'s lesions, like the standard for finding all facts in the Vaccine Program, is a preponderance of the evidence. . . . It is not possible to date the beginning of Mr. C.'s lesions with absolute certainty, but absolute certainty is not required." Entitlement Decision at 13 (citing *Moberly*, 592 F.3d at 1322; *Knudsen*, 35 F.3d at 549; *Andreu*, 569 F.3d at 1380; *Bunting v. Secretary of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991)). Based on the "persuasive testimony of Dr. Venkates[a]n," the special master found that it was more likely than not that Mr. C.'s lesions existed before his vaccination. Entitlement Decision at 13.

Mr. C. argues that the special master's conclusion was arbitrary and capricious, and points to additional evidence which cuts against the special master's conclusion. Dr. Tornatore testified that Mr. C.'s symptoms on December 24, 2004, represented inflammatory and enhancing lesions, and Dr. Venkatesan agreed that the lesions were likely enhancing on December 24. Pet'r's Mem. at 15 (citing Tr. 375:9-18 (Nov. 17, 2009) (Dr. Tornatore)); Tr. 391:2-12 (Nov. 17, 2009) (Dr. Venkatesan)). Mr. C. argues that the Cotton article supports the claim that a lesion enhancing on December 24 could have healed by December 30. The Cotton article states, "[T]he duration of [lesions'] enhancement is clearly skewed toward enhancement duration of [two] weeks and less." Ex. 27, Tab A, at 642 (cited in Pet'r's Mem. at 16). Moreover, "[t]he distribution of new enhancing lesions according to the duration of their enhancement is skewed toward enhancement duration of one week and less, suggesting that more frequent MR follow-up would unveil average duration of enhancement much closer to that found in animal models of the disease." Ex. 27, Tab A, at 643. An acute animal model demonstrated that enhancement did not last for more than five days.[15] *Id*. If Mr. C. had enhancing lesions on

[14]This latter reasoning is not necessarily persuasive, taken by itself. Although there were six lesions, and a lesion generally has a 50% chance of lasting two weeks, it does not necessarily follow that each of Mr. C.'s lesions had a 50% chance of remaining enhanced for two weeks, independent of the others. Instead, it is likely the lesions would have been affected by similar variables and that their healing rates would have been relatively coextensive and comparable than six lesions randomly selected in six different individuals.

[15]A chronic animal model showed lesions lasting from five days to five weeks. Ex. 27, Tab A, at 643. Chronic animal models would be analogous to individuals who develop chronic

December 24, it would therefore be reasonable to believe that the lesions stopped enhancing by December 30, six days later.

In sum, Mr. C. has provided evidence that lesions that were caused after his vaccination and were enhancing on December 24 could have appeared unenhanced on the MRI conducted on December 30. Indeed, the court is inclined to believe this order of events is more likely than not to be accurate. However, the court must review the special master's findings under the arbitrary and capricious standard. The special master concluded that because none of the six lesions were enhancing on December 30, it was more likely than not that they had originated prior to Mr. C.'s vaccination on December 13. Although new enhancing lesions appear to last a shorter period of time, *see* Ex. 27, Tab A, at 643, that does not demonstrate that the special master's reasoning was capricious. Few facts are certain in this case. The Cotton article discusses an average range of time during which lesions are likely to enhance, based on a study that can only estimate how long a lesion is enhancing within a thirteen-day period. Although it is possible Mr. C.'s lesions developed after December 13 and enhanced for a short period of time, it is also quite possible that they predated his vaccination and enhanced for two weeks or more. Were the court deciding this matter *de novo*, it would be a close call. In the circumstances, the special master's finding cannot be deemed arbitrary, capricious, or an abuse of discretion. Accordingly, the special master's denial of Mr. C's direct-causation claim is upheld.

C. *Petitioner's Significant-Aggravation Claim*

1. *Use of the* Loving *test.*

Mr. C. contends that the special master failed to use the correct test to evaluate his significant-aggravation claim. The special master applied the six-factor test developed in *Loving* for evaluating significant-aggravation off-table vaccine claims. Entitlement Decision at 13-14 (quoting *Loving*, 86 Fed. Cl. at 144). The petitioner argues in his brief that the special master who decided Mr. C.'s case created the *Loving* test, and he contends that the test is "arbitrary and capricious, an abuse of . . . discretion, and not in accordance with the law." Pet'r's Mem. at 27-28. That argument is wrong. The *Loving* test, in fact, first appears in this court's decision of the same name, in which the court reasoned that a petitioner should prevail on a significant-aggravation off-table claim by establishing the three *Althen* prongs as well as three elements identified by the Federal Circuit in a table significant-aggravation claim case, *Whitecotton*, 81 F.3d 1099.[16] By applying the *Loving* test, the special master followed the pertinent and appropriate standard for addressing Mr. C.'s alternative significant-aggravation claim — as he was obliged to do.

2. *Factual findings concerning significant-aggravation.*

The special master concluded that Mr. C. had failed to establish by preponderant evidence the fourth prong of the *Loving* test (which is also the first prong of the *Althen* test) —

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progressive multiple sclerosis, rather than relapsing remitting multiple sclerosis. *See* Hr'g Tr. 57:16 to 58:1 (Jun. 14, 2011).

[16]The court's path in developing the six-factor test is described *supra*, at 9.

"a medical theory causally connecting" the aggravation of his multiple sclerosis to the vaccination. Mr. C. maintains that he met this burden and the special master's decision was "arbitrary, an abuse of discretion, and not in accordance with the law." Pet'r's Mem. at 31.

The special master considered Dr. Tornatore's theory linking Mr. C.'s multiple sclerosis symptoms with his vaccination. Specifically, Dr. Tornatore hypothesized that portions of the flu vaccine mimicked the structure of a component of the central nervous system, myelin basic protein ("MBP"). *See* Tr. 23:2-12 (Nov. 4, 2008) (Dr. Tornatore). He postulated that the similarity in the molecular structure of the vaccine and MBP could have led Mr. C.'s immune system to attack both the antigen from the vaccine and the MBP native to Mr. C. *See* Entitlement Decision at 17; Tr. 23:2 to 24:25 (Nov. 4, 2008) (Dr. Tornatore). Both Dr. Tornatore and Dr. Venkatesan agreed that this kind of antigen cross-reaction can occur in some circumstances. For example, it is generally accepted that antigen cross-reactions play a role in the development of Sydenham's chorea after a streptococcus bacteria infection. *See* Entitlement Decision at 17; Tr. 24:2 to 26:22 (Nov. 4, 2008) (Dr. Tornatore); Tr. 147:10 to 149:1 (Nov. 4, 2008) (Dr. Venkatesan).

In support of his view that an antigen cross-reaction could aggravate Mr. C.'s multiple sclerosis, Dr. Tornatore relied primarily on an article by Kai Wucherpfennig. *See* Ex. 19 (Kai W. Wucherpfennig & Jack L. Strominger, *Molecular Mimicry in T Cell-Mediated Autoimmunity: Viral Peptides Activate Human T-Cell Clones Specific for Myelin Basic Protein*, 80 Cell 695 (1995)). Additional support for Dr. Tornatore's position was found in numerous case reports which reported the appearance of acute demyelinating conditions following vaccinations. Entitlement Decision at 20; *see* Tr. 63:3 to 67:5 (Nov. 4, 2008) (Dr. Tornatore) (discussing the case reports); Ex. 12, Tab B (Rohit Bakshi & John C. Mazziotta, *Acute Transverse Myelitis After Influenza Vaccination: Magnetic Resonance Imaging Findings*, 6 J. Neuroimaging 248 (1996)); Ex. 12, Tab D (Naoko Nakamura et al., *Neurologic Complications Associated with Influenza Vaccination: Two Adult Cases*, 42 Internal Medicine 191 (2003)); Ex. 12, Tab E (A.J. Larner & S.F. Farmer, *Myelopathy following influenza vaccination in inflammatory CNS disorder treated with chronic immunosuppression*, 7 European J. of Neurology 731 (2000)).

The Wucherpfennig article described a study which tested several viral and bacterial peptides that seemed to share a molecular structure with myelin basic protein. Wucherpfennig tested the peptides, including several portions from the influenza A virus, to see if they stimulated the production of T-cells. Ex. 19 at 695-96; Tr. 117:10 to 118:19 (Nov. 4, 2008) (Dr. Tornatore) (describing the Wucherpfennig study). While three portions of the influenza A virus did not produce many T-cells, one portion led to a large response. Entitlement Decision at 18. Dr. Tornatore believed this result supported his theory that the flu virus could contain peptides similar to myelin basic protein and that those peptides could cause an immune reaction. Tr. 118:13 to 119:3 (Nov. 4, 2008) (Dr. Tornatore).

The special master rejected Dr. Tornatore's theory, believing it less likely than not to be biologically plausible. He observed that the Wucherpfennig study tested the influenza A virus, not the flu vaccine, and noted "[t]he difference between the influenza vaccine and the influenza virus could be significant." Entitlement Decision at 18. As the special master put it, "[d]ifferent portions of the influenza A virus caused different reactions," with one stimulating a large

production of T-cells and the others not, and "there is no evidence that the portions of the influenza virus that mimicked myelin basic protein are the portions of the virus used in the influenza vaccine." *Id*.; *see also* Tr. 101:11-16 (Nov. 4, 2008) (Dr. Tornatore) ("[W]e have no idea what . . . influenza proteins [were] . . . in [the vaccine administered to Mr. C.]."). Additionally, the Wucherpfennig study was conducted *in vitro*, and Dr. Venkatesan was unconvinced that the results of an *in vitro* study could be extrapolated to cases involving human beings. Tr. 155:20 to 156:15 (Nov. 8, 2004) (Dr. Venkatesan).

The special master also reviewed a study in which patients with multiple sclerosis were given the influenza vaccine. Two and four weeks after the vaccination, their blood was tested to see if they developed an increased number of T-cells that reacted with myelin basic protein. The study found a "lack of increased responses of autoreactive T cells during vaccination." Ex. A, Tab 5 (N.F. Moriabadi, et al., *Influenza vaccination in MS: Absence of T-cell response against white matter proteins*, 56 Neurology 938, 943 (2001)); *see also* Tr. 171:2-20 (Nov. 4, 2008) (Dr. Venkatesan). The authors stated their study could "reduce concerns about a putative triggering of autoimmune responses by mechanisms such as molecular mimicry." Ex. A, Tab 5, at 943. The Moriabadi article thus functions as evidence that the findings in the Wucherpfennig article might not extend to situations involving the flu vaccine.

The special master did not find the Wucherpfennig article and the case reports cited by Dr. Tornatore sufficient to establish, by preponderant evidence, a biologically plausible theory linking Mr. C.'s vaccination and aggravation of multiple sclerosis. Particularly, the special master found the findings of the Wucherpfenning article were undermined by the Moriabadi study.

Moreover, he found that any inference of causation from the case reports that demyelinating conditions could be caused by the flu vaccine was undercut by three articles, submitted by the government, reporting how the flu vaccine affects people already afflicted with multiple sclerosis. One study involving 643 multiple sclerosis patients "suggest[ed] that commonly administered vaccinations (specifically, against tetanus, hepatitis B, and influenza) d[id] not increase the risk of relapse in patients with multiple sclerosis." Ex. A, Tab 1 (Christian Confavreux, et al., *Vaccinations and the Risk of Relapse in Multiple Sclerosis*, 344 New England J. of Medicine 319, 324 (2001)). A second study, involving 440 case subjects and 950 control subjects, "did not find any increased relative risks regardless of the timing of vaccination, indicating that vaccinations do not cause [central nervous system] demyelination, nor do they trigger its clinical manifestation in those with subclinical disease." Ex. A, Tab 2 (Frank DeStephano, et al., *Vaccinations and Risk of Central Nervous System Demyelinating Diseases in Adults*, 60 Arch. Neurol. 504, 507 (2003)). In a third study, researchers "conducted a multicenter, prospective, randomized, double-blind trial of influenza immunization in patients with relapsing/remitting [multiple sclerosis]." *See* Ex. A, Tab 3 (A.E. Miller, et al., *A multicenter, randomized, double-blind placebo-controlled trial of influenza immunization in multiple sclerosis*, 48 Neurology 312, 312 (1997)). One hundred and four patients were divided into two groups, one of which received the flu vaccine and the other of which received a placebo. "The two groups showed no [statistically significant] difference in attack rate or disease progression over 6 months. Influenza immunization in [multiple sclerosis] patients is neither associated with an increased exacerbation rate in the postvaccination period nor a change in

disease course over the subsequent 6 months." *Id*. Additionally, when the American Academy of Neurology commissioned the MS Council for Clinical Practice Guidelines to address "the safety of immunization in patients with MS, particularly . . . the risk of relapse after vaccination[,]" the researchers concluded that "there is definitive evidence against a substantial increased risk of MS exacerbation after influenza vaccine." Ex. A, Tab 4 (Oliver T. Rutschmann, et al., *Immunization and MS: A summary of published evidence and recommendations*, 59 Neurology 1837, 1837, 1840 (2002)). Considering these studies, Dr. Venkatesan concluded that Dr. Tornatore's theory was "extremely unlikely," although not impossible. Tr. 149:13 to 150:21 (Nov. 4, 2008).

The special master concluded that Mr. C. had not established by preponderant evidence "'a medical theory causally connecting [his] significantly worsened condition to [his] vaccination.'" Entitlement Decision at 23 (quoting *Loving*, 86 Fed. Cl. at 144). Mr. C. asserts this finding is arbitrary and capricious for several reasons. First, he contends that the Wucherpfennig article demonstrates the possibility of the theory that the flu vaccine can aggravate multiple sclerosis. *See* Pet'r's Mem. at 29. Second, he notes that Dr. Venkatesan agreed that while there is not an increase of multiple sclerosis in patients who have had the flu, there "does appear to be an increase in exacerbations of [multiple sclerosis] in patients who have upper respiratory illnesses in general, of which influenza is one." Tr. 137:24 to 138:3 (Nov. 4, 2008) (Dr. Venkatesan). Finally, Mr. C. points out that the Confavreux article showed an increase in exacerbations in MS patients after receiving flu shots at a rate almost double that of the control group, even if that rate was not found by the authors to be statistically significant. *See* Pet'r's Mem. at 30 (citing Ex. A, Tab 1). The Miller study, while not showing a *statistically significant* increase in multiple sclerosis exacerbations, also reported that almost twice as many multiple sclerosis patients who received a flu vaccine suffered exacerbations compared to those who had received a placebo. *See* Ex. A, Tab 3, at 313.[17]

The evidence in this case is so closely balanced that the decision could have gone either way. The government's expert, Dr. Venkatesan, agreed that Dr. Tornatore's theory was not impossible, and the Confavreux and Miller articles indicate that flu vaccinations were correlated with an increase in exacerbations of multiple sclerosis symptoms. More relevantly, while the government's studies are evidence that the flu vaccine does not *generally* cause aggravations of multiple sclerosis, they do not show that it is implausible that the flu vaccine could cause aggravations of multiple sclerosis in some patients. An overwhelming percentage of the population will not have a negative reaction to particular vaccines, but that does not prove that those vaccines never cause medical complications.

Nonetheless, the court cannot say that the special master's findings were arbitrary. Although case reports alone have been enough to satisfy the "plausible theory" prong, *see Rotoli*,

[17]The study explained, "Forty-nine patients received influenza vaccine and 54 patients received placebo. . . . During the 28 days after inoculation, three vaccine patients and two placebo patients experienced MS exacerbations (no significant difference). Over the 6-month follow-up period, vaccine patients experienced 11 attacks (annual rate 0.45) and placebo patients, 6 attacks (annual rate 0.22). The difference in attack rates was not statistically significant." Ex. A, Tab 3, at 313.

89 Fed. Cl. at 86-87, the studies provided by the government suggest it might be incorrect to conclude that the chronological picture painted by the case reports illustrates anything other than correlation. The Moriabadi study also undercuts the argument that the findings of the Wucherpfennig article extend to the flu vaccine.

Having considered each of the petitioner's arguments, the special master's Entitlement Decision will be upheld.

II. Redaction Decision

The Vaccine Act provides that, "[a] decision of a special master or the court in a proceeding shall be disclosed," with an explicit exception for "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." 42 U.S.C. § 300aa-12(d)(4)(B)(ii). "[I]f the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information." *Id.*[18] Mr. C. has requested that his name be redacted, or alternatively, that information concerning his medical records be redacted from the special master's opinion prior to publication. Pet'r's Mem. In Support of Mot. for Review of Redacted Decision ("Pet'r's Redaction Mem."). The government resists any redactions. Resp't's Resp. to Pet'r's Br. Regarding Redaction ("Resp't's Redaction Mem.").

A. *Standard for Review*

Notwithstanding the fact that the special master's Redaction Decision turned virtually entirely upon issues of statutory interpretation, the government urges the court to regard the special master's decision to deny redaction as an exercise of discretion. *See* Resp't's Redaction Mem. at 4. The court cannot accept this contention by the government. It is axiomatic that the court "owe[s] no deference to the . . . special master on questions of law." *Broekelschen*, 618 F.3d at 1345. Statutory construction is a matter of law, reviewed de novo. *Hawkins v. United*

[18] In full, 42 U.S.C. § 300aa-12(d)(4)(B) provides:

> A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information
>
> (i) which is trade secret or commercial or financial information which is privileged and confidential, or
>
> (ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,
>
> and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

Vaccine Rule 18(b) mirrors the language of 42 U.S.C. § 300a-12(d)(4)(B).

States, 469 F.3d 993, 1000 (Fed. Cir. 2006); *see also Commercial Energies, Inc. v. United States*, 929 F.2d 682, 684 (Fed. Cir. 1991) ("The construction of [a] statute is a question of law which we review de novo.") (citing *Frank's Livestock & Poultry Farm, Inc. v. United States*, 905 F.2d 1515, 1517 (Fed. Cir. 1990)). In the circumstances of this case, the court treats the issue of redaction as a question of law with a relatively minimal attendant question of applying law to the facts.

In determining the meaning of a particular statutory term or phrase, the "starting point must be the language employed by Congress." *American Tobacco Co. v. Patterson*, 456 U.S. 63, 68 (1982) (internal quotations omitted). "Where the intent [of a statute] is unambiguously expressed by the plain meaning of the statutory text, we give effect to that clear language." *Sharp v. United States*, 580 F.3d 1234, 1237 (Fed. Cir. 2009). However, the meaning of the phrase "clearly unwarranted invasion of privacy" is not plainly understood by reference to the text alone. "[W]here a statute is of doubtful meaning . . . the court may look into prior and contemporaneous acts, the reasons which induced the act in question, the mischiefs intended to be remedied, the extraneous circumstances, and the purpose intended to be accomplished by it, to determine its proper construction." *Hamilton v. Rathbone*, 175 U.S. 414, 419 (1899). Statutory interpretation requires courts to "read[] the whole statutory text, consider[] the purpose and context of the statute, and consult[] any precedents or authorities that inform that analysis." *Dolan v. United States Postal Serv.*, 546 U.S. 481, 486 (2006). Accordingly, the court will look to the context and legislative history of the Vaccine Act to elucidate the nature of a "clearly unwarranted invasion of privacy," as well as how similar language has been interpreted in other correlative contexts.

B. *Statutory Evolution of the Vaccine Act*

Congress passed the Vaccine Act in 1986 for purposes of aiding "development of new vaccines [and] the improvement of existing vaccines[,] and . . . to compensate the victims of vaccine-related injuries." H.R. Rep. No. 99-908, at 1 (1986). The Senate Committee report concerning the 1986 legislation noted the importance of public access to information about adverse vaccine reactions. The Committee stated that it "believe[d] that information regarding the adverse reactions to childhood vaccines[,] including locality and State of immunization, date of the vaccination, information concerning reported symptoms, manifestation of resulting illness, disability, or injury and name of the health care provider should be a matter of public record." S. Rep. No. 99-483, at 17-18 (1986). The Committee concurrently attached much less importance to disclosure of the names of those adversely affected by vaccines, noting that it "d[id] not believe that the name of the individual who suffered an adverse reaction need be available to the public." *Id*. at 18.

As part of the Vaccine Act as adopted in 1986, Congress provided measures to protect the privacy of those whose health had been affected by vaccines. First, individual-identifying information submitted to government agencies could not be disclosed to the public, notwithstanding provisions of the Freedom of Information Act ("FOIA") providing otherwise. *See* 42 U.S.C. § 300aa-25(c)(1) (Supp. V 1988) ("Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of Title 5 [the Freedom of

Information Act], or otherwise, to any person except . . . the person who received the vaccine, or . . . the legal representative of such person."); 42 U.S.C. § 300aa-25(c)(2) (Supp. V 1988) ("[T]he term 'information which may identify an individual' shall be limited to[,]" among other things, "the name . . . of the person who received the vaccine."). Second, information submitted by parties during the compensation proceedings should not be disclosed to outside parties, absent the consent of the person who submitted the information. *See* 42 U.S.C. § 300aa-12(c) (Supp. V 1988) ("Information submitted to a special master in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without express consent of the person who submitted the information.").[19]

Three years later, Congress amended the Vaccine Act. *See* Pub. L. No. 101–239, § 6601, 103 Stat. 2106, 2285 (1989). The 1989 amendments were largely designed to effectuate the original goals of the 1986 Vaccine Act, namely, the creation of "a compensation procedure that administered awards 'quickly, easily, and with certainty and generosity.'" H.R. Rep. No. 101-247, at 509 (1989) (citing H.R. Rep. No. 99-908). The House Committee disapproved of the early experience under the 1986 Act, expressing regret that "all participants ha[d], to some degree, maintained their traditional adversarial litigation postures." H.R. Rep. No. 101-247, at 510. The Committee reiterated "its intent that the vaccine injury compensation system be informal, flexible, and expeditious" and "its expectation that the [s]pecial [m]aster . . . will allow the proceedings to be direct and straightforward." *Id*. As part of the 1989 amendments, Congress added the privacy provision that became 42 U.S.C. § 300aa-12(d)(4)(B). The operative language of the 1989 amendment Congress adopted in 42 U.S.C. § 300aa-12(d)(4)(B)(ii) — calling for redactions to prevent "a clearly warranted invasion of privacy" — mirrored the words of an exemption to FOIA disclosure obligations which had been enacted twenty years earlier — barring disclosures that would be "a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). As previously noted, Congress had shown an awareness of the provisions of FOIA in crafting the text embodied in the original 1986 enactment of the Vaccine Act.

C. *Analogous Language in the Freedom of Information Act*

FOIA requires the government to make available public information, excepting, among other things, "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). This provision in FOIA was enacted in 1966 and has not been changed since. *See* Pub. L. No. 89-487, 80 Stat. 250 (1966). The direct parallel between this exemption in FOIA and the privacy provision added by the 1989 amendments to the Vaccine Act is instructive. "[W]here two statutes use similar language we generally take this as a 'strong indication that [they] should be interpreted *pari passu*.'" *Smith v. City of Jackson*, 544 U.S. 228, 260 (2005) (quoting *Northcross v. Board of Educ.*, 412 U.S. 427, 428 (1973) (per curiam)).

[19]This text was moved to a different subsection of 42 U.S.C. § 300aa-12 after subsequent amendments to the Vaccine Act. *See* 42 U.S.C. § 300aa-12(d)(4)(A) (2006) ("Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.")

Paragraph 552(b)(6), commonly called Exemption 6 to FOIA, has been the subject of several decisions by the Supreme Court, including especially for purposes of this case, *United States Dep't of State v. Ray*, 502 U.S. 164 (1991). In *Ray*, the Court considered whether the disclosure of records of interviews of unsuccessful Haitian emigrants constituted "a clearly unwarranted invasion of personal privacy" when the records disclosed the names and other identifying information of the interviewees, but that information had been redacted. *Id*. at 165, 173. The Court explained, "The question in this case is whether petitioner has discharged its burden of demonstrating that the disclosure . . . adequately served the statutory purpose [of FOIA] and that the release of the information identifying the particular [persons] would constitute a clearly unwarranted invasion of their privacy." *Id*. at 175.

Paragraph 552(b)(6) "requires the Court to balance 'the individual's right of privacy' against the basic policy of opening 'agency action to the light of public scrutiny.'" *Ray*, 502 U.S. at 175 (quoting *Department of Air Force v. Rose*, 425 U.S. 352, 372 (1976)). Even when "the interest in protecting the privacy of the redacted information is substantial, [the court] must still consider the importance of the public interest in its disclosure. For unless the invasion of privacy is 'clearly unwarranted,' the public interest in disclosure must prevail." *Ray*, 502 U.S. at 177. However, the Court opined that redaction of personal information may serve statutory purposes, *i.e.*, if the "public interest [would be] adequately served by disclosure of the redacted [documents,] disclosure of the unredacted documents would . . . constitute a clearly unwarranted invasion of . . . privacy." *Id*. at 178.

The notion of privacy "encompasses the individual's control of information concerning his or her person." *United States Dep't of Justice v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 763 (1989).[20] Even when "'an event is not wholly 'private,'" an individual retains an "'interest in limiting disclosure or dissemination of the information.'" *Reporters Comm.*, 489 U.S. at 770 (quoting Wm. Rehnquist, *Is an Expanded Right of Privacy Consistent with Fair and Effective Law Enforcement?*, Nelson Timothy Stevens Lectures, University of Kansas Law School, pt. 1, 13 (Sept. 26-27, 1974)).

"It is well established that identifying information such as names, addresses, and other personal information falls within the ambit of privacy concerns under FOIA." *Associated Press v. United States Dep't of Def.*, 554 F.3d 274, 285 (2d Cir. 2009); *see also Rose*, 425 U.S. at 380-81 (recognizing privacy interest served by redaction of identifying information about cadets present in summaries arising out of ethics hearings at the Air Force Academy); *Ray*, 502 U.S. at 175-77, (reasoning privacy interest in names of interviewees is significant where their names could then be linked to other personal information in records of interviews); *Maynard v. Central Intelligence Agency*, 986 F.2d 547, 566-67 (1st Cir. 1993) (holding that a person's name, place of birth, address, and occupation constitute examples of information, the disclosure of which would constitute a significant invasion of privacy). "Although disclosure of . . . personal information

[20]Although "*Reporters Committee* involved [Exemption 7, 5 U.S.C. 552(b)(7)(C),] its discussion governs [Exemption 6], for the noted differences bear only on the type of information sought and the degree of invasion to a privacy interest that will be tolerated." *Federal Labor Relations Auth. v. United States Dep't of Veterans Affairs*, 958 F.2d 503, 510 (2d Cir. 1992).

constitutes only a *de minimis* invasion of privacy when the identities of the interviewees are unknown, the invasion of privacy becomes significant when the personal information is linked to particular [people]." *Ray*, 502 U.S. at 176.

D. *The Special Master's Decision*

In his Redaction Decision, the special master abjured any reference to, or reliance upon, the context and legislative history of the privacy provision of the Vaccine Act and the virtually identical provision in FOIA. Instead, the special master focused exclusively upon the common law history of access to judicial decisions, and specifically on precedent in the Ninth Circuit relating to designation of anonymous plaintiffs in civil cases. *See* Redaction Decision, at 2-4 (citing, quoting, and analyzing *Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006)).[21]

The special master's analogy to the public's right to access to judicial files is inapposite to petitions filed and decisions rendered under the Vaccine Act. Proceedings under the Vaccine Act are designed to be quite different from civil proceedings in court. In proposing the 1989 Amendments, the House Committee explained that "[t]he [Vaccine Act compensation] system was intended to be 'fair, simple, and easy to administer' . . . . The powers of discovery within the proceeding were given over to the [m]aster, . . . in order 'to replace the usual rules of discovery in civil actions in Federal Courts.'" H.R. Rep. No. 101-247, at 509-10 (quoting H.R. Rep. No. 99–908). While all court documents are publicly accessible in civil proceedings by default, absent a specific and persuasive reason to the contrary, no documents filed as part of a Vaccine Act petition can be accessed by the public apart from the published decisions of the special master and reviewing courts. *See* 42 U.S.C. § 300aa-12(d)(4). This difference was established by Congress because of the different public interests in civil proceedings and Vaccine Act proceedings. As the Federal Circuit has noted, the Vaccine Act encourages resolution of claims in the Vaccine Program and discourages civil litigation over such claims where similar privacy protections are not provided. *See Zatuchni v. Secretary of Health & Human Servs.*, 516 F.3d 1312, 1316 (Fed. Cir. 2008).[22]

[21]The Ninth Circuit's criteria for allowing anonymous designations of plaintiffs can be draconian in application and result. *See Doe v. Kamehameha Schools/Bernice Pauahi Bishop Estate*, 625 F.3d 1182 (9th Cir. 2010) (order denying rehearing en banc of a decision refusing to allow anonymous designation of plaintiffs), *id*. at 1182 (Kozinski, C. J., dissenting from denial of rehearing en banc), *id*. at 1184 (Reinhardt, J. with whom Kozinski, C. J. joins, also dissenting from denial of rehearing en banc).

[22]The court of appeals in *Zatuchni* noted that proceedings under the Vaccine Act are supposed to be an "expeditious[] and informal" means of compensating persons injured by vaccines. 516 F.3d at 1316 (quoting 42 U.S.C. § 300aa-12(d)(2)(A)). Indeed, "[t]he Act requires that . . . a petition [seeking compensation for a vaccine injury] be filed, and judgment from the Program rejected, prior to bringing an action in state court." *Id*. at 1316 n.3 (citing 42 U.S.C. § 300aa-11(2)(A)-21).

This right to access public records in civil cases is justified by the interest of citizens in "keep[ing] a watchful eye on the workings of public agencies." *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 598 (1978). In contrast, the purposes of the Vaccine Act are to compensate those injured by vaccines and to disseminate information to the public about vaccines. *See* H.R. Rep. No. 99-908, at 1; S. Rep. No. 99-483, at 18 (explaining the Vaccine Act is "designed to widen the knowledge about adverse reactions to childhood vaccines" and noting "the primary method of reducing adverse [vaccine] reactions [in] children is through an informed public"). These purposes are not served by requiring petitioner's names to be published even where an objection is made on reasonable grounds. Such disclosure may discourage potential petitioners from filing new cases, thus tending to inhibit public awareness of vaccines and their risks. Importantly, in this vein, the Senate Committee Report on the bill that became the Vaccine Act in 1986 specified that the committee "d[id] not believe that the name of the individual who suffered an adverse reaction need be available to the public." S. Rep. No. 99-483, at 18.

In light of the different public purposes behind disclosure in civil and vaccine cases, and the strength of the analogy between the terms of FOIA and the Vaccine Act, the special master erred in relying on precedents in the Ninth Circuit regarding criteria for designation of anonymous plaintiffs as a basis for construing the privacy provisions of the Vaccine Act.

E. *Synthesis*

The privacy provisions of the Vaccine Act should be construed in concert with the privacy provisions of FOIA, which the Vaccine Act provisions manifestly mirror. The matching statutory terms constitute words of art that convey a particular meaning for both contexts. Accordingly, the court finds that it is appropriate to balance Mr. C.'s right of privacy against the public purpose of the Vaccine Act, in a manner analogous to the balancing of private and public interests under FOIA.

Mr. C. seeks redaction of either his name or his medical condition. The release of either of these types of information would constitute a substantial invasion of privacy. As the Supreme Court noted in *Ray*, "the invasion of privacy becomes significant when the personal information is linked to particular [people]." 502 U.S. at 176. Redaction would be necessary to prevent Mr. C.'s name from being "linked" to information concerning his medical condition.[23]

Mr. C.'s interest must be weighed against the government's interest in public disclosure.[24] As previously described, the Vaccine Act aims to increase public awareness of

[23]The government points out that redacting Mr. C.'s name would not necessarily keep his identity a secret. However, even when information "is not wholly private[,]" an individual retains an "interest in limiting disclosure or dissemination of the information." *Reporters Comm.*, 489 U.S. at 770 (internal quotations omitted).

[24]In the FOIA context, the Supreme Court has narrowly defined the "public interest" relevant to balancing under Exemption 6 as "the extent to which disclosure would serve the core purpose of the FOIA, which is contribut[ing] significantly to the public understanding of the

vaccines and the medical conditions they may cause. Effecting this goal requires public access to information about vaccinations and ensuing conditions. Disclosure of Mr. C.'s medical condition constitutes a significant invasion of privacy. However, because of the notable public interest in Mr. C.'s vaccination, subsequent medical history, and claim of an adverse reaction, the court cannot say that disclosure of his medical information necessarily constitutes an *unwarranted* invasion of privacy. In contrast, there is no public interest in the disclosure of Mr. C.'s name. Mr. C.'s identity has no effect on the public's awareness of vaccines and their potential risks. He has a rational concern that disclosure of his identity would have potential adverse consequences to his ability to perform his assigned work responsibilities. Indeed, where "[t]here is no relevant public purpose to be weighed against [a] threatened invasion[,] . . . *any* invasion of privacy threatened by disclosure . . . is 'clearly unwarranted.'" *Federal Labor Relations Auth.*, 958 F.2d at 513.

Mr. C.'s name shall be redacted from the special master's Entitlement and Redaction Decisions.

CONCLUSION

For the reasons stated, petitioner's motion for review of the special master's Entitlement Decision is DENIED, but his motion for review of the special master's Redaction Decision is GRANTED. The special master's Entitlement Decision is AFFIRMED, while the special master's decision denying redaction is REVERSED. The case is REMANDED to the special master for further proceedings in accord with this decision. Petitioner shall have twenty days to submit to the special master proposed redactions in the special master's decisions.

It is so ORDERED.

s/ Charles F. Lettow
Charles F. Lettow
Judge

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operations or activities of the government." *Department of Def.*, 510 U.S. at 495 (quotations and emphasis omitted).